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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,924	09/21/2001	Hideaki Yagi	Q66252	2470

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SUGHRUE MION ZINN MACPEAK & SEAS, PLLC
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EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/956,924

Applicant(s)

YAGI ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 1-12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The use of the trademark SIROOCO® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
3. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.
4. The disclosure is objected to because the applicant has used sixth paragraph, means-plus-function language to define features of the applicants' invention. Accordingly, the examiner requires the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicants to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000)).

Appropriate correction is required.

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Claim Objections

5. Claims 2, 3, 9 and 10 objected to for the following reasons. In claims 2 and 9 the applicants recites "a continuous base flow rate when a breath-synchronized operation is not performed, which represents a flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously." The nature of a flow rate that "represents" another flow rate is not clear from the specification, the claims or the prior art.

6. In order to increase the clarity of the claims the examiner suggests that the applicants correct the above clauses to read "a continuous base flow rate that is the flow rate at which the oxygen apparatus can supply oxygen-enriched gas continuously", or "which third flow rate that is the flow rate at which the oxygen enriching apparatus can supply the oxygen-enriched gas continuously".

7. In addition, claims 1-5 are objected to because the applicants has evoked sixth paragraph, means-plus-function language to define features of the applicants' invention. Therefore the examiner objects to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required. The applicants are invited to review the claims and make like corrections and clarifications where necessary.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 1-5, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 4,706,664 to *Snook et al.*

10. *Snook et al* disclose a supplemental oxygen apparatus that includes means for supplying oxygen-enriched gas either intermittently in conjunction with a patient's breathing cycle or continuously that includes all of the features recited in claims 1, 3-5, 11 and 12.

11. For example, in the embodiment described in FIG 19 means (the same or equivalent of those disclosed by the applicant) for supplying oxygen enriched gas at a first flow rate equal to or less than the rate at which the apparatus can supply the oxygen-enriched gas continuously include demand solenoid valves (22 and 26). See, e.g., column 6, lines 39-51 and column 9, lines 44-52.

12. Means for supplying the oxygen enriched gas at a second flow rate greater than the continuous base flow rate during an inhalation period having a length 25 to 40% of a user's breathing cycle during a breath-synchronized operation is performed include a pressure sensor (102), control circuit (1200) and valves (22 and 26). See, e.g., column 6, lines 39-65 and column 13, lines 7-30.

13. With respect to claim 2, *Snook et al* disclose that the means that comprise control valves (20, 22) that establish a continuous flow mode of operation. See column 6, lines 39-51. *Snook et al* further disclose that the base flow rate may be set to as low as one liter per minute. See, e.g., the paragraph bridging columns 12 and 13.

14. With respect to claims 3-5, *Snook et al* disclose means for detecting the state of inhalation or exhalation based on the output of the sensor including the control circuitry (1200) and valves,

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which determines the timing of the supply of oxygen over one or a number of inhalations or exhalations. See, e.g., column 12, lines 22-40.

15. With respect to claim 10, *Snook et al* also disclose a switch as recited in the form of selector 73. See, e.g., column 11, lines 33-38.

16. With respect to claims 11 and 12 *Snook et al* discloses a controller and recording medium as recited in the form of controller 1200 and its ROM for example.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 4,706,664 to *Snook et al* in view of in view of US patent no. 6,237,594 to *Davenport*.

19. *Snook et al* disclose all of the features recited in claim 17 except one or more tanks in series in the oxygen-enriched-gas supply passage.

20. However, the use of one or more tanks in an oxygen supply passage was known at the time of invention. For example, *Davenport* discloses an oxygen supply device wherein a number of tanks (i.e., boluses 46 and 50) are used to allow the device to deliver a broad range of flow to the patient without negatively impacting the performance of the valves and sensors. A check valve (62) is provided between the boluses. See column 5, lines 60-68.

21. Accordingly, it would have been obvious to one with ordinary skill in the art to modify the *Snook et al* device to include additional tanks in the gas supply line as taught by *Davenport* in

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order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

22. Regarding the size of the tanks recited in claim 9, although the size of the tanks/boluses is not expressly disclosed, it is well known that the greater the size of the buffer tanks, the greater the efficiency in delivering gas to a patient over a wide range of flow rates. See, e.g., the discussion of Table 4 of US patent no. 4,681,099 to *Sato et al.* Accordingly, because the applicants does not disclose that a tank sized at 500ml or more solves a problem or provides an advantage not addressed in the prior art, it would have been an obvious design choice to provide tanks having at least 500 ml capacity in order to efficiently provide the range of desired flow rates.

Additional Pertinent Prior Art

23. The following prior art is pertinent to the applicant's disclosure: US patent nos. 6,378,520 to *Davenport*, 5,626,131 to *Chua et al*, 5,137,017 to *Salter*, and 4,686,974 to *Sato et al.*

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR

June 26, 2003

A handwritten signature in black ink, appearing to be 'MAN'.A handwritten signature in black ink, appearing to be 'GKD'.

GLENN K. DAWSON
PRIMARY EXAMINER